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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,657	05/29/2007	Hans Grundei	F0506-1US (E 2452 US)	1641
54380 7590 11/28/2008 FLASTER/GREENBERG P.C. 8 PENN CENTER 1628 JOHN F. KENNEDY BLVD. 15TH FLOOR PHILADELPHIA, PA 19103			EXAMINER MONTANO, MELISSA ANN	
			ART UNIT 3738	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,657	Applicant(s) GRUNDEI, HANS	
	Examiner MELISSA MONTANO	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 September 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/27/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed 9/2/2008 has been entered. Claims 1-14 remain pending in this application. The previous 112 rejections have been withdrawn in light of Applicant's explanation and amendment to the claims. The previous objections have been withdrawn in light of Applicant's amendments to the drawings and specification.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,824,096 to Pappas et al. (Pappas).

Pappas teaches a hinge knee replacement device that is implanted into the femur and tibia (col. 3, lines 23-27). The hinge assembly (300) of the device (100) includes circular cylindrical shaft (adaptation tube; 313) that is press-fit (sealed in the intracorporal direction) into a frusto-conical bushing (spacer/bush; 340) (col. 4, lines 26-32). The bushing is so dimensioned such that it can displace axially in the tapered cavity (503) of the tibial body (501). The examiner asserts that since the bushing is placed into a tapered cavity, it necessarily widens from the extracorporal direction to the intracorporal direction, as shown in fig. 14. Pappas also teaches that the bushing surface (smooth surface; 342) articulates with the polished inner tapered cavity (503) of the tibial body (501) (col. 4, lines 51-53). The examiner asserts that articulation with the cavity of the tibial body would necessarily require the bushing surface to be smooth. Further, Pappas teaches a second cavity (505) that supports a stabilizing rod (502) for insertion into the tibia (700). The examiner asserts that the second cavity (505) would

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necessarily constitute an extracorporeal coupling device, as claimed by applicant. Further still, the edge of the shaft (adaptation tube; 313) is in communication with the second cavity (505) via a reduced diameter portion (shoulder; 508) of the second cavity (extracorporeal coupling device; 505), as shown in fig. 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 3, 5, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pappas.

Pappas teaches the mounting according to claims 1 and 6. However, Pappas does not explicitly teach the claimed length ratio of the widening bush or an antibacterial/titanium bush or adaptation tube. The examiner asserts that this ratio could be determined through routine experimentation, particularly in absence of any disclosed criticality for the claimed ratio, in order to obtain the desired coupling strength and ease of connection. See MPEP § 2144.04. Pappas further teaches preferred metal materials for the different components include titanium alloy with a ceramic titanium nitride coating (col. 6, lines 27-30), which would necessarily constitute a plated titanium bush surface and a titanium-coated adaptation tube, as claimed by applicant. The examiner asserts that titanium can be interpreted as an antibacterial effect because it is a well known body-compatible material and does not encourage the growth of bacteria.

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5. Claims 4, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pappas in view of US Patent No. 4,615,705 to Scales et al. (Scales).

Pappas teaches the mounting according to claims 3 and 6. However, Pappas does not teach that the bush or adaptation tube is made with silver.

Scales teaches that silver is a known material used for surgical implants, for the purpose of providing a localized antimicrobial effect (col. 1, lines 42-43 and 62-64). The examiner asserts that the surgical implants, taught by Scales, would necessarily include the mounting, bush (Pappas' bushing; 340) and adaptation tube (Pappas' shaft; 313), as claimed by applicant.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the mounting of Pappas to include a silver-plated bush surface and adaptation tube plated/constructed out of silver, in order to provide a localized antimicrobial effect, as taught by Scales.

6. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pappas in view of US Patent Application Publication No. 2003/0171825 A1 to Blunn et al. (Blunn).

Pappas teaches the mounting according to claim 6. However, Pappas does not teach the use of hydroxyapatite or calcium phosphate.

Blunn teaches that hydroxyapatite, or calcium phosphate, is a known material used for the purpose of encouraging osseous integration (page 1, paragraphs 11-12).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the mounting of Pappas to include the use of hydroxyapatite

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and/or calcium phosphate for coating the adaptation tube, in order to encourage osseous integration, as taught by Blunn.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pappas in view of *Cementless Titanium Tapered-Wedge Femoral Stem* by Marshall et al. (Marshall).

Pappas teaches the mounting according to claim 6. However, Pappas does not teach a plasma titanium spray coating for the adaptation tube.

Marshall teaches that plasma titanium spray is a known material that can be used for the purpose of contributing to long-term bone or tissue ingrowth (page 547, 3rd full paragraph, lines 1-3 and page 549, 1st full paragraph, lines 10-15).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the mounting of Pappas to include the use of plasma titanium spray for coating the adaptation tube in order to contribute to long-term tissue ingrowth, as taught by Marshall.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pappas in view of WO 99/64491 to Spaans et al. (Spaans).

Pappas teaches the mounting according to claim 6. However, Pappas does not teach the use of polyurethane for the construction of the adaptation tube.

Spaans teaches that polyurethane is a biomedical material that is used to process implants, for the purpose of having good mechanical properties (page 1, lines 15-20).

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It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the mounting of Pappas to include an adaptation tube constructed out of polyurethane in order to provide an adaptation tube having good mechanical properties, as taught by Spaans. Further, it has been held that the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination. See MPEP § 2144.07.

Response to Arguments

9. Applicant's arguments, see pages 7-9, filed 9/2/2008, with respect to the rejection(s) of claim(s) 1, 3, and 5 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the teachings of Pappas.

10. Applicant's arguments, see pages 9-14, filed 9/2/2008, with respect to the rejection(s) of claims(s) 2, 4, and 6-14 under 35 USC 103(a) have been fully considered but they are not persuasive.

11. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

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In this case, motivation for the rejections is found in the references applied and in the knowledge generally available to one having ordinary skill in the art. The examiner agrees that Scales teaches antimicrobial surgical implants and asserts that this would necessarily include the mounting taught by Pappas, which is sufficient reasoning to combine the references. The examiner agrees that Blunn teaches the use of a surface treatment transcutaneous prosthesis that encourages osseous integration such as hydroxyapatite (which is a hydrated calcium phosphate) and asserts that this reason is sufficient for the combination of the Blunn reference with the mounting taught by Pappas. The examiner asserts that the Marshall reference is combinable with the mounting taught by Pappas because it addresses the use of a titanium plasma spray for contributing to long-term tissue ingrowth. The examiner agrees that Spaans teaches polyurethane suitable for biomedical applicants, including implants such as the mounting taught by Pappas.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA MONTANO whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738